IDEVAX™

DATA SHEET

VAX-ID® 2200

PRODUCT INFORMATION

Product	VAX-ID® 2200
Description	Intradermal injection adaptor for easy, accurate, and standardized injection of medicinal products in the skin. The adaptor is single use and can be provided sterile and non-sterile (to be sterilized before use). It can be preconfigured with different needle gauges and allow for a predefined penetration depth.
Classification	Class IIa medical device determined by Rule 6 for a surgically invasive device intended for transient use.
Materials	Polypropylene (PP) and Stainless Steel (needle)
Dimensions	40 x 29 x 17 mm (Device) | 150 x 75 x 17 mm (Pouch)
Weight	± 4 grams
Intended Purpose	VAX-ID® is an injection adaptor for easy and reliable intradermal injection of medicinal products at a predefined penetration depth.
Intended User	Professional medical care trained personnel (e.g. nurse, doctor, pharmacist…).
Intended Population	All ages and populations.
Indications for use	Intradermal injection of approved medical substances.
Contra-indications	Do not use on wounds, scars, nor damaged skin.

DEVICE CONFIGURATIONS UDI 5430003573000022000000UC

REF Number Sterile	REF To be Sterilized	Needle Gauge	Average Injection Depth	Needle Tip Length
D00046	D00037	32G	0.5mm	0.85mm
D00048	D00036	30G	0.6mm	1.15mm
D00047	D00035	27G	0.8mm	1.55mm

VAX-ID® IS TO BE USED IN COMBINATION WITH THESE MEDICAL DEVICES

Draw Needle	Commercially available draw needle
Small volume syringe with luer slip tip	Commercially available 1.0 mL syringe with luer slip tip like HSW Soft-Ject, Low Dead Space or B.Braun Injekt®-F Luer Solo

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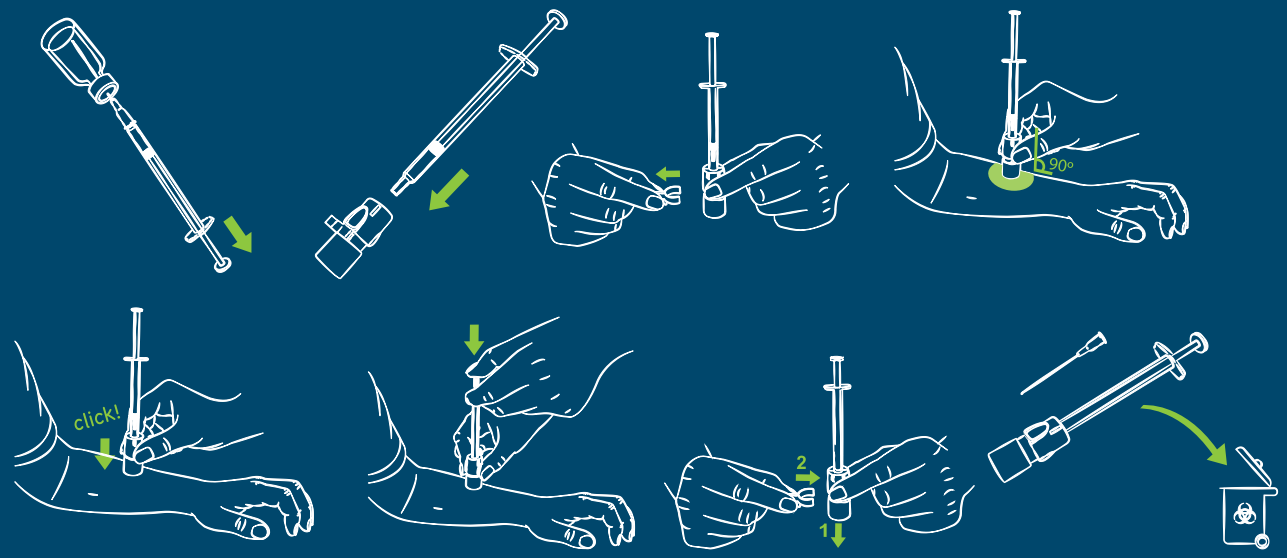
PACKAGING, STORAGE, AND SHELF-LIFE

Packaging	Boxes of 100 devices
Materials	See-through pouch of medical grade PET/PP foil and paper
Storage	Recommended temperature: 10-30°C Dry environment No direct sunlight Without large temperature fluctuations
Shelf-life	5 years
Warnings	Do not use if package is damaged or open. Single Use Only. Re-use may lead to contamination by foreign material/organisms thus infection and/or illness. Dispose of used device in a sharp's container in accordance with applicable national regulations. Any serious incidence (as defined per the European Medical Device Regulation 2017/745) should be reported to the manufacturer and the competent Authority.

CE 1282 MD 10°C 30°C

INSTRUCTIONS FOR USE



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